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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/063,515	05/01/2002	Audrey Goddard	10466/300	8122

30313 7590 06/13/2007

KNOBBE, MARTENS, OLSON & BEAR, LLP
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EXAMINER	
ROMEO, DAVID S	

ART UNIT	PAPER NUMBER
1647	

MAIL DATE	DELIVERY MODE
06/13/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/063,515	GODDARD ET AL.	
	Examiner	Art Unit	
	David S. Romeo	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 March 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *0307*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☒ Other: *See Continuation Sheet*.

Continuation of Attachment(s) 6). Other: Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 03/12/2007 has been entered.

Claims 1–5 are pending and being examined.

Interview Summary

In a telephone interviews with AnneMarie Kaiser on May 7, 2007 and Brenden Gingrich on May 9, 2007 the examiner discussed the following proposed examiner's amendment to the claims, which would have resolved all the outstanding issues:

1. An isolated antibody that specifically binds to the polypeptide ~~having the amino acid sequence of amino acids 34-321~~ of SEQ ID NO: 10.

7. (New) An isolated antibody that specifically binds to the polypeptide encoded by the cDNA deposited under ATCC accession number 209922.

8. (New) The antibody of claim 7 which is a monoclonal antibody.

9. (New) The antibody of claim 7 which is a humanized antibody.

10. (New) The antibody of claim 7 which is an antibody fragment.

11. (New) The antibody of claim 7 which is labeled.

However, the examiner hereby withdraws the proposed amendment.

Maintained Formal Matters, Objections, and/or Rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants argue that:

> This argument is not persuasive, as it ignores a fundamental principle of the written description requirement - all that is required to satisfy the written description requirement is that "the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed." M.P.E.P. §2163.02 (internal citations omitted, emphasis added).
>
> Applicants have indicated in the specification that that "other methionine residues located either upstream or downstream from the amino acid position 1 in the figures may be employed as the starting amino acid residue for the PRO polypeptides." The instant case is similar to a generic chemical structure with a variable "R" group that is defined in the specification. Where the genus of chemicals defined by the structure is small (e.g. 8), the fact that a genus is described does not prevent the applicant from claiming a particular species by selecting a particular "R" group -the description of the small genus and various "R" groups is sufficient.
>
> In the instant application, there are eight methionine residues in SEQ ID NO:10. At a minimum, as the Examiner has acknowledged, there is generic written description support for the "genus" of proteins starting at any one of these methionine residues. This "genus" contains eight immediately identifiable species since SEQ ID NO:10 is disclosed, and one of skill in the art knows which residues are methionine. Given the "generic" description, combined with the specifics of SEQ ID NO:10, each of the eight species in the "genus" is adequately described. This is particularly true for the claimed species, since methionine #34 is the first methionine in SEQ ID NO: 10. Applicants request that the Examiner clarify what is meant by, and explain his basis for requiring, "evidence of record that amino acid #34 is employed as a start site," as Applicants are not aware of any support for this test in the M.P.E.P. or the case law.

Applicants' arguments have been fully considered but they are not persuasive. Firstly, the disclosure is not limited to the disclosure of a small genus of only eight species located downstream from the amino acid position at position 1 of SEQ ID NO: 10 because applicants

have indicated in the specification that "other methionine residues located either upstream or downstream from the amino acid position 1 in the figures may be employed as the starting amino acid residue for the PRO polypeptides." Secondly, the specification does not specifically indicate which methionine residue(s) located either upstream or downstream from amino acid position 1 in SEQ ID NO: 2 is employed as the starting amino acid residue for the PRO874 polypeptide. Thirdly, there is no evidence of record that amino acid #34 is employed as a start site. Therefore, the generic disclosure of what may be possible or conceivable does not convey with reasonable clarity to those skilled in the art that Applicants were in possession of the invention as now claimed. The disclosure in this case amounts to a generic disclosure of every possible start site and does not reasonably lead those skilled in the art to any particular start site. Therefore, the examiner concludes that the "amino acids 34-321 of SEQ ID NO: 10" limitation is not supported in the original disclosure and constitutes new matter.

New Formal Matters, Objections, and/or Rejections:

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Sequence Rule Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth below or on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. The paper copy of the sequence listing is missing. Although applicants indicate that a file containing

the sequence was attached to the Transmittal Form filed 05/01/2002, the paper copy of the sequence listing is not of record and needs to be replaced.

Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1–5 are rejected under 35 U.S.C. 102(b) as being anticipated by Baker (WO 99/63088).

As indicated above, the examiner has concluded that the "amino acids 34-321 of SEQ ID NO: 10" limitation is not supported in the original disclosure and constitutes new matter. This rejection is based upon an effective filing date of 05/01/2002, the filing date of the present application, for the claimed antibodies.

Baker discloses an isolated polypeptide (page 55, full paragraph 4) that is identical to the amino acid sequence of SEQ ID NO: 10, as indicated below (Qy = SEQ ID NO: 10):

```
Query Match             100.0%;  Score 1709;  DB 21;  Length 321;
Best Local Similarity   100.0%;  Pred. No. 2.4e-181;
Matches  321;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;
```

```
Qy          1 RTRGRTRGGCEKVPINTSCNPTAHLVNSSCPGLMCVFQGYSSKGLIQRSVFNLQIYGVLG 60
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db          1 RTRGRTRGGCEKVPINTSCNPTAHLVNSSCPGLMCVFQGYSSKGLIQRSVFNLQIYGVLG 60

Qy         61 LFWTLNWVLALGQCVLAGAFASFYWAFHKPQDIPTFPLISAFIRTLRYHTGSLAFGALIL 120
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db         61 LFWTLNWVLALGQCVLAGAFASFYWAFHKPQDIPTFPLISAFIRTLRYHTGSLAFGALIL 120

Qy        121 TLVQIARVILEYIDHKLRGVQNPVARCIMCCFKCCLWCLEKFIKFLNRNAYIMIAIYGKN 180
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        121 TLVQIARVILEYIDHKLRGVQNPVARCIMCCFKCCLWCLEKFIKFLNRNAYIMIAIYGKN 180

Qy        181 FCVSAKNAFMLLMRNIVRVVVLDKVTDLLLFFGKLLVVGGVGVLSFFFFSGRIPGLGKDF 240
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        181 FCVSAKNAFMLLMRNIVRVVVLDKVTDLLLFFGKLLVVGGVGVLSFFFFSGRIPGLGKDF 240

Qy        241 KSPHLNYYWLPIMTSILGAYVIASGFFSVFGMCVDTLFLCFLEDLERNNGSLDRPYYMSK 300
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        241 KSPHLNYYWLPIMTSILGAYVIASGFFSVFGMCVDTLFLCFLEDLERNNGSLDRPYYMSK 300

Qy        301 SLLKILGKKNEAPPDNKKRKK 321
              |||||||||||||||||||||
Db        301 SLLKILGKKNEAPPDNKKRKK 321.
```

Baker also discloses monoclonal, polyclonal, and humanized antibodies, and antibody fragments that bind the isolated polypeptide (page 280, last full paragraph; page 367, full paragraph 3; page 309, full paragraph 3; page 311, line 28, through page 313, line 6; pages 365-371).

Claims 1–5 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Afar (U. S. Publication No. 20050019870).

Afar discloses a prostate tumor associated gene (designated 24P4C12) and its encoded protein. 24P4C12 is highly expressed in prostate tissue xenografts, providing evidence that it is turned on in at least some prostate cancers. 24P4C12 provides a diagnostic and/or therapeutic target for prostate and other cancers. See Abstract and Example 3, page 76.

24P4C12 comprises an amino acid sequence that is identical to amino acids 34–321 of SEQ ID NO: 2, as indicated below (Qy = SEQ ID NO: 2; Db = 24P4C12):

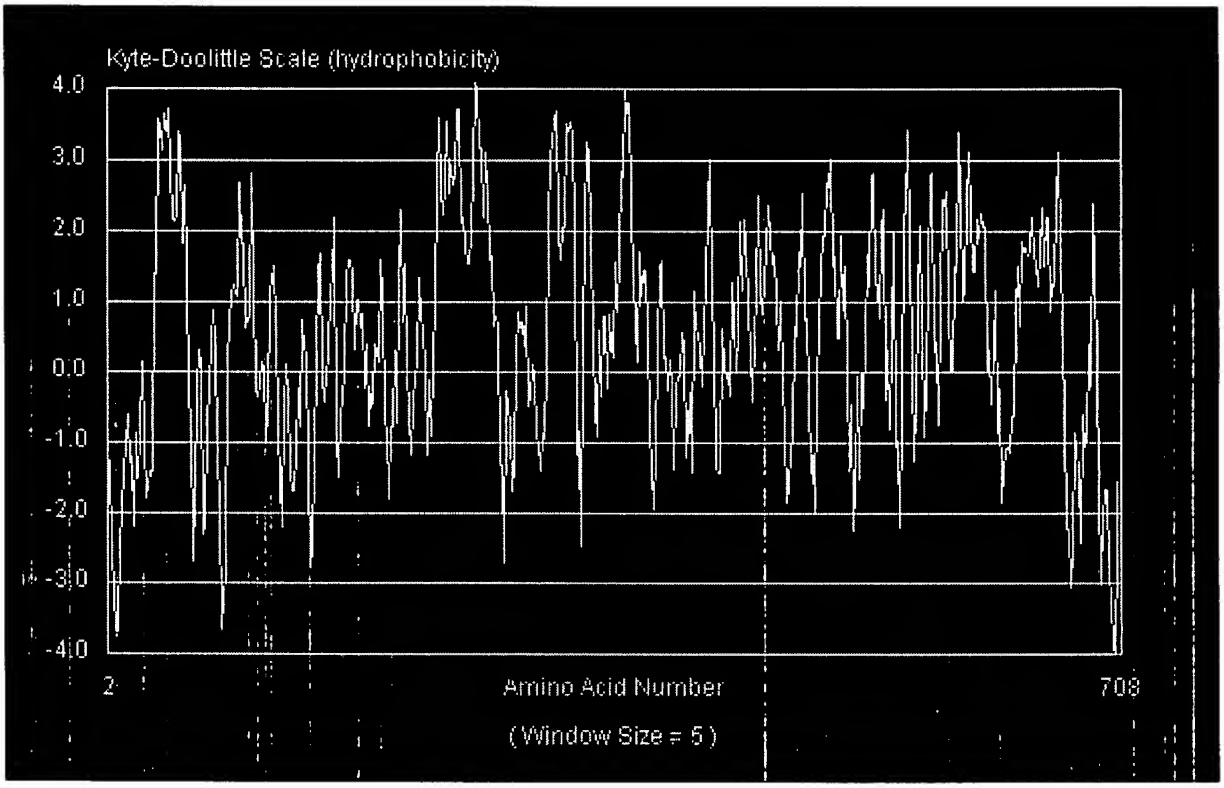
```
Query Match .           97.5%;  Score 1667;  DB 3;  Length 710;
Best Local Similarity   100.0%;  Pred. No. 2.7e-176;
```

```
  Matches  313;  Conservative    0;  Mismatches    0;  Indels    0;  Gaps    0;

Qy          9 GCEKVPINTSCNPTAHLVNSSCPGLMCVFQGYSSKGLIQRSVFNLQIYGVLGLFWTLNWV 68
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        398 GCEKVPINTSCNPTAHLVNSSCPGLMCVFQGYSSKGLIQRSVFNLQIYGVLGLFWTLNWV 457

Qy         69 LALGQCVLAGAFASFYWAFHKPQDIPTFPLISAFIRTLRYHTGSLAFGALILTLVQIARV 128
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        458 LALGQCVLAGAFASFYWAFHKPQDIPTFPLISAFIRTLRYHTGSLAFGALILTLVQIARV 517

Qy        129 ILEYIDHKLRGVQNPVARCIMCCFKCCLWCLEKFIKFLNRNAYIMIAIYGKNFCVSAKNA 188
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        518 ILEYIDHKLRGVQNPVARCIMCCFKCCLWCLEKFIKFLNRNAYIMIAIYGKNFCVSAKNA 577

Qy        189 FMLLMRNIVRVVVLDKVTDLLLFFGKLLVVGGVGVLSFFFFSGRIPGLGKDFKSPHLNYY 248
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        578 FMLLMRNIVRVVVLDKVTDLLLFFGKLLVVGGVGVLSFFFFSGRIPGLGKDFKSPHLNYY 637

Qy        249 WLPIMTSILGAYVIASGFFSVFGMCVDTLFLCFLEDLERNNGSLDRPYYMSKSLLKILGK 308
              ||||||||||||||||||||||||||||||||||||||||||||||||||||||||||||
Db        638 WLPIMTSILGAYVIASGFFSVFGMCVDTLFLCFLEDLERNNGSLDRPYYMSKSLLKILGK 697

Qy        309 KNEAPPDNKKRKK 321
              |||||||||||||
Db        698 KNEAPPDNKKRKK 710.
```

Afar discloses and claims anti-24P4C12 antibodies, including monoclonal, polyclonal, and humanized antibodies as well as fragments containing the antigen binding domain and/or one or more complementarity determining regions of these antibodies and labeled forms thereof (page 38, line 25 through page 43, line 12).

Regions of the 24P4C12 protein that show immunogenic structure, as well as other regions and domains, can readily be identified using various other methods known in the art, such as Chou-Fasman, Garnier-Robson, Kyte-Doolittle, Eisenberg, Karplus-Schultz or Jameson-Wolf analysis (page 34, full paragraph 3).

The following is a Kyte-Doolittle plot of 24P4C12:



Regions with values above 0 are hydrophobic in character.

Anti-24P4C12 antibodies that specifically bind epitopes in the 398–710 amino acid region of 24P4C12 will also specifically bind SEQ ID NO: 10 because this region of 24P4C12 is identical to amino acids 34–321 of SEQ ID NO: 10. Applicant has the burden of distinguishing between anti-24P4C12 antibodies and the claimed antibodies.

Alternatively, it would have been obvious to one of ordinary skill in the art at the time of Applicants' invention to identify hydrophilic regions in the 24P4C12 structure and to make anti-24P4C12 antibodies that recognize the hydrophilic regions, with a reasonable expectation of success. Anti-24P4C12 antibodies that specifically bind epitopes in the 398–710 amino acid region of 24P4C12 will also specifically bind SEQ ID NO: 10 because this region of 24P4C12 is identical to amino acids 34–321 of SEQ ID NO: 10. One of ordinary skill in the art would be

motivated to make this modification in order to detect 24P4C12 in prostate samples. The invention is prima facie obvious over the prior art.

Afar has an effective filing date of 04/12/1999, which is obtained via U.S. Provisional application No. 60/128,858.

According to M.P.E.P. § 715.II.B., an affidavit or declaration under 37 CFR 1.131 is not appropriate in situations where the reference U.S. patent or U.S. patent application publication claims the same patentable invention.

Conclusion

No claims are allowable.

ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (571) 272-0890. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 9:00 A.M. TO 5:30 P.M. IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY NICKOL, CAN BE REACHED ON (571)272-0835.

IF SUBMITTING OFFICIAL CORRESPONDENCE BY FAX, APPLICANTS ARE ENCOURAGED TO SUBMIT OFFICIAL CORRESPONDENCE TO THE CENTRAL FAX NUMBER FOR OFFICIAL CORRESPONDENCE, WHICH IS (571) 273-8300.

CUSTOMERS ARE ALSO ADVISED TO USE CERTIFICATE OF FACSIMILE PROCEDURES WHEN SUBMITTING A REPLY TO A NON-FINAL OR FINAL OFFICE ACTION BY FACSIMILE (SEE 37 CFR 1.6 AND 1.8).

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING MAY BE OBTAINED FROM THE PATENT APPLICATION INFORMATION RETRIEVAL (PAIR) SYSTEM. STATUS INFORMATION FOR PUBLISHED APPLICATIONS MAY BE OBTAINED FROM EITHER PRIVATE PAIR OR PUBLIC PAIR. STATUS INFORMATION FOR UNPUBLISHED APPLICATIONS IS AVAILABLE THROUGH PRIVATE PAIR ONLY. FOR MORE INFORMATION ABOUT THE PAIR SYSTEM, SEE HTTP://PAIR-DIRECT.USPTO.GOV. CONTACT THE ELECTRONIC BUSINESS CENTER (EBC) AT 866-217-9197 (TOLL-FREE) FOR QUESTIONS ON ACCESS TO THE PRIVATE PAIR SYSTEM,

/DAVID ROMEO/
PRIMARY EXAMINER
Art Unit 1647

DSR
JUNE 9, 2007

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES	Application No. 10/063,515	Applicant(s) GODDARD ET AL.	
	Examiner David S. Romeo	Art Unit 1647	

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

☒1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).

☒2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).

☐3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).

☐4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."

☐5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).

☐6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).

☐7. Other:

Applicant Must Provide:

☐ computer readable form (CRF) copy of the "Sequence Listing".

☒ An initial paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.

☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (571)272-2510
For CRF Submission Help, call (571)272-2501/2583
PatentIn Software Program Support (SIRA)

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Technical Assistance.....................703-287-0200
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